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The effect of local anaesthesia on postoperative pain and hemostasis after dental rehabilitation under general anaesthesia in pediatric patients

Submission date
31/12/2022

Recruitment status
No longer recruiting

Registration date
08/01/2023

Overall study status
Completed

Last Edited
12/03/2025

Condition category
Oral Health

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dental caries, also known as tooth decay, is a common disease that affects children. It has multiple causes and its treatment can be challenging, especially when the child is uncooperative. In such cases, dental treatment under general anaesthesia may be used. However, the use of local anaesthesia as an alternative is a controversial issue. The aim of the study is to investigate the effects of using local anaesthesia on post-operative pain and bleeding after dental treatment under general anaesthesia in children.
This research aims to study the effect of local anaesthesia on postoperative pain and hemostasis after Dental rehabilitation under general anaesthesia.

Who can participate?
Children of both genders aged three to seven years, described by Frankel's behavior rating scale as definitely negative.

What does the study involve?
The usage or not of local anaesthesia agents when treating children under general anaesthesia.

What are the possible benefits and risks of participating?
One of the benefits is the reduction in both pain and bleeding post-operatively as mentioned in some studies.
The risk of using local anaesthesia when treating children under general anaesthesia is an overdose of the used agent and the interaction with general anaesthesia agents.

Where is the study run from?
Al Bashir hospital (Jordan)

When is the study starting and how long is it expected to run for?

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Amal Batarseh, amal_batarseh@yahoo.com

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
The effect of local anaesthesia on postoperative pain and hemostasis after dental rehabilitation under general anaesthesia in pediatric patients aged from three to seven years old

Study objectives
Local anaesthesia effects on postoperative pain and hemostasis

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/02/2020, Scientific Research Ethics Committee (Ministry of Health, ALhashimi Alshamaly, Basman Erea, Hay Naifah, Next to Prince Hamazah Hospital, P.O.Box: 86, Amman, Jordan; +9625200230; no email provided), ref: Moh/REC/2020/44

Study design
Single-arm parallel-design single-blinded randomized controlled study

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Post operative pain following dental treatment under general anaesthesia

Interventions
Forty-six boys and girls were included in this single-arm, parallel-design, single-blinded, randomized, controlled study. Before the commencement of the study, numbers from one to forty-six were randomly assigned as with local anaesthesia (LA) or without LA in closed envelope.

Group A: given LA which is (2% weight/volume (w/v) lidocaine with 1:80000 epinephrine) by calculating the dose according to the provided formula not exceeding 4.4 mg/kg.
Group B: not given any extra medication

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain measured using:
1. Universal-pain-assessment-tool (UPAT) before the operation
2. FLACC behavior scale immediately after treatment, 30 min and 6 hours

Key secondary outcome(s))
Hemostasis measured using bleeding score obtained immediately after extraction using the Boezaart-surgical-field-grading-scale.

Completion date
01/03/2022

Eligibility

Key inclusion criteria

1. Aged three to seven years
2. Described by Frankel’s behavior rating scale as definitely negative.
3. Arabic-speaking and healthy, with an American Society of Anesthesiologists (ASA) I or II classification

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
3 years

Upper age limit
7 years

Sex
All

Total final enrolment
43

Key exclusion criteria
1. Needing treatment or extraction of permanent teeth
2. Having an either medical, mental, or physical impairment
3. Need only restorative treatment without extraction or vice versa

Date of first enrolment
01/03/2020

Date of final enrolment
01/03/2022

Locations

Countries of recruitment
Jordan

Study participating centre
Al Bashir hospital
Amman
Jordan
-

Sponsor information

Organisation
Jordan Ministry of Health

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
amal_batarseh@yahoo.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/11/2023	12/03/2025	Yes	No
Other unpublished results	Participant flow diagram		13/02/2023	No	No
Other unpublished results			13/02/2023	No	No
Participant information sheet	Participant information sheet		04/01/2023	No	Yes
Participant information sheet		11/11/2025	11/11/2025	No	Yes